

**REMARKS**

Claims 21-47 are pending. Claims 37 and 46 are amended to remove the extraneous term “member”, as requested by the Examiner.

Claims 21-37, 39-46 stand rejected under 35 U.S.C. 102 (e) as being anticipated by Tovey (U.S. Patent No. 5,478,354). Applicants traverse the rejection.

Claim 21, as amended, requires, among other elements, a *generally annular-shaped ring* defining a plane, the ring being disposed about a central axis extending through the plane; at least two staple members extending from the ring, each of the at least two staple members having at least a distal portion formed of an elastic material, the distal portions having a first configuration, where the distal portions are separated by a first distance and *wherein the distal portions are substantially parallel to the central axis*, and a second configuration, where the distal portions are separated by a second distance, the second distance being less than the first distance; and a member configured to be disposed within the ring, the member configured to bias the distal portions of the at least two staple members to the first configuration when the member is disposed within the ring.

The Examiner references two embodiments of Tovey relative to the claimed invention. The first is depicted at Figures 8 and 9 and is described at column 4, lines 32-44 of the specification. The second embodiment of Tovey is depicted at Figures 10 and 11 and is described at column 4, line 44 to column 5, line 19 of the specification. These two embodiments are described separately in Tovey; they do not function together. As a result, Applicants analyze each separately.

**The First Tovey Embodiment**

The first Tovey embodiment is described as a surgical fastener comprising a Y-shaped base 82 having leg portions 84 integral therewith. As moveable collar 88 is moved over the Y-shaped base 82 it moves leg portions 84 from a first position to a second position.

The first Tovey embodiment does not teach or suggest the invention of claim 21. As discussed above, claim 21 requires a generally annular-shaped ring and at least two staple members that extend from the ring. The first Tovey embodiment does not teach or suggest a ring having at least two staple members extending from the ring. The device of the first Tovey embodiment is a Y-shaped fastener having legs extending therefrom. Element 88, described as a moveable collar does not have staple members extending from it.

Further, the first Tovey embodiment does not teach or suggest the last element of claim 21--a member configured to bias the distal portions of the at least two staple members to the first configuration *when the member is disposed within the ring*. Tovey does not describe the requisite ring, and therefore can not describe a member that is disposed within the ring.

Claims 22-38 that depend from claim 21 are also allowable over this first Tovey embodiment as they depend from claim 21 and for other reasons that will be omitted for brevity's sake.

For similar reasons, Applicants submit that the first Tovey embodiment does not teach or suggest the elements of claim 39. Claim 39 claims a system that includes a device comprising: a ring disposed about a central axis and at least two staple members extending therefrom, the at least two staple members each having a distal end; and a member configured to be disposed within the ring; and wherein the device has a first configuration, where the member is disposed within the ring, and a second configuration, where the member is not disposed within the ring, and wherein the distal ends of the at least two staple members are substantially parallel to the central axis when the device is in the first configuration, and the distal ends of the at least two staple members are substantially orthogonal to the central axis when the device is in the second configuration.

As described above with respect to claim 21, the first Tovey embodiment does not teach or suggest a ring or a member configured to be disposed within the ring. As such, Applicants submit that claim 39 and those claims that depend from claim 39 are allowable.

#### The Second Tovey Embodiment

The Examiner has also suggested that the second embodiment of Tovey anticipates the claimed invention. The second embodiment is depicted at Figures 10 and 11 and is described at column 4, line 44 to column 5, line 19 of the specification.

The second Tovey embodiment does not teach or suggest the invention claimed in claim 21. As discussed above, the device of claim 21, requires, among other elements, a generally annular-shaped ring defining a plane, the ring being disposed about a central axis extending through the plane; at least two staple members extending from the ring, each of the at least two staple members having at least a distal portion formed of an elastic material, the distal portions having a first configuration, where the distal portions are separated by a first distance and *wherein the distal portions are substantially parallel to the central axis*, and a second configuration, where the distal portions are separated by a second distance, the second distance being less than the first distance; and a member configured to be disposed within the ring, the member configured to bias the distal portions of the at least two staple members to the first configuration when the member is disposed within the ring.

In particular, Tovey does not teach or suggest that the distal portions of the at least two staple members are substantially parallel to the central axis of the ring when the at least two staple members are in the first configuration; i.e., when the member is disposed within the ring. The second Tovey embodiment depicts a fastener configured to fit outside a cannula. The fastener has legs 94 that extend from a bottom surface of a base 92. The legs 92 have camming surfaces 98 abut the cannula when the cannula resides within the base.

In contrast to the invention claimed in claim 21, Tovey's legs 94 are not "substantially parallel to the central axis of the ring". Instead, following the profile of legs 94 away from base 92, legs 94 undulate away from the central axis, then toward the central axis to form cam surface 98, and then back away from the central axis, before ending in a barb 96 that points toward the central axis. As a result, legs 94 can not be considered to be substantially parallel to the central axis of the ring.

Further, with respect to the dependent claims, the second Tovey embodiment also does not teach or suggest the elements of at least claims 24 and 37. Claim 24 depends from claim 21 and further requires that the distal portion of the at least two staple members are substantially orthogonal to the central axis when the distal portions are in the second configuration.

Reviewing Figure 10 of Tovey, barbs 96 are not substantially orthogonal to the central axis when the cannula 99 is not disposed within base 92. Claim 37 also depends from claim 21, and further requires that the ring have an inner periphery and the at least two staple members member extend from the inner periphery.

Further, the second Tovey embodiment does not anticipate claim 39 or its dependents for reasons similar to those described above. Claim 39 claims a system for engaging tissue having a preexisting opening that includes: a device comprising a ring disposed about a central axis and at least two staple members extending therefrom, the at least two staple members each having a distal end; and a member configured to be disposed within the ring; and wherein the device has a first configuration, where the member is disposed within the ring, and a second configuration, where the member is not disposed within the ring, and wherein the distal ends of the at least two staple members are substantially parallel to the central axis when the device is in the first configuration, and the distal ends of the at least two staple members are substantially orthogonal to the central axis when the device is in the second configuration. Tovey does not teach or suggest that the distal ends are substantially parallel to the central axis when the device is in the first configuration. Nor does Tovey teach or suggest that distal ends of the at least two staple members are substantially orthogonal to the central axis when

the device is in the second configuration. Claim 46 is allowable for reasons similar to those discussed with respect to claim 37.

Claims 38 and 47 stand rejected under 37 USC § 103(a) as being unpatentable over Tovey. Applicants traverse the rejection.

Claim 38 depends from claim 37 and requires that the at least two staple members comprise at least four staple members, and each of the at least four staple members extend from the *inner periphery* of the ring at positions that are angularly offset with respect to one another by substantially the same angle. The legs 94 of Tovey do not extend from the inner periphery of the ring. Instead, they extend from the bottom surface of base 92, as is shown in Figures 10 and 11. As a result, Tovey does not teach or suggest the elements of claim 38 or similarly claimed elements in claim 47, and Applicants seek withdrawal of the rejection.

Examiner's October 16, 2007, Response

Applicants have reviewed the argument set forth on page 5 of the October 16, 2007, Office Action, and continue to submit that the claims define over Tovey. In reviewing Figure 10 of Tovey, it is difficult to determine what angle the distal ends 96 make with the central axis, so Applicants will not comment on what is shown in Figure 10.

Applicants submit, however, that the distal ends 96 depicted in Figure 11 of Tovey can not fairly be described as substantially parallel to the central axis. If one draws a tangent line off of the distal end 96, it intersects the central axis at what appears to be a forty-five degree angle. Even if you considered the distal end to start somewhere proximal of the very tip, for instance closer to where the reference numeral 94 or 98 is indicated, that section of the tip moves through an arc whose tangents converge toward the central axis, then diverge from the central axis and finally converge toward the central axis. As such, only two tangent lines drawn from the curving legs 96 will be parallel with the central axis at spaced-apart points where the staple arms curve away and toward the central axis. The distal portions of

the staple arms are simply not substantially parallel with the central axis when they are in the first configuration (biased by the member).

For the foregoing reasons, Applicants submit that claims 21-47 are allowable over the cited art, and request the Examiner to withdraw the rejections.

Respectfully submitted,

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